15 May 2020

Louise Clarke
Assistant Secretary
Office of Health and Technology Assessment Policy
Department of Health
PO Box 9848
Canberra ACT 2601

Dear Ms Clarke

RE: PBS Public consultation on the post-market review of medicines for smoking cessation

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the opportunity to provide feedback on the post-market review of medicines for smoking cessation and addresses the terms of reference most relevant to hospital pharmacists where they have the greatest impact. According to the Australian Institute of Health and Welfare's (AIHW) latest report on *Alcohol, tobacco & other drugs in Australia*[1], tobacco is identified as the leading cause of morbidity and mortality in Australia. Tobacco use contributes to the burden for eight disease groups including 41% of respiratory disease, 22% of cancers, 12% of cardiovascular disease, 6.8% of infections and 3.7% of endocrine disorders.

Our members working in Australian hospitals report that acute care settings are an important and significant intervention point for patients who smoke as those who attend are often critically ill, vulnerable and are encouraged to make a smoking cessation attempt. Many people who smoke and happen to be hospitalised with cardiovascular[2,3,4], respiratory or neurological conditions report being prepared and making efforts to quit, as do those who attend emergency departments and attribute their attendance to a smoking-related problem. In response, many hospitals have developed smoking cessation services for inpatients, leveraging critical intervention opportunities to support patients in initiating their quit journey and discharge patients with appropriate smoking cessation medicines.

Hospital Pharmacist-led smoking cessation programs have been reported to have significant impact on patients who smoke. Some hospital programs that supported patients to stop smoking prior to an impending surgery, showed that the assessment and brief interventional advice provided by Hospital Pharmacists, which includes the provision of smoking cessation medicines where appropriate, resulted in patients being four times more likely to make a quit attempt and two times more likely to be smokefree on the day of surgery, than those who received the usual ad-hoc quit advice. Hospital outpatient smoking cessation clinics have also been shown to achieve cessation rates of approximately 42%[5].

Terms of Reference 1: Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines.

Hospital pharmacists have reported that Australian national clinical guidelines for smoking cessation are of limited relevance to the acute setting. With an absence of National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines for smoking cessation, the latest edition of the Royal Australian College

of General Practitioners (RACGP) *Supporting smoking cessation: A guide for health professionals* guidelines[6] is key resource utilised by health professionals supporting patients on their quit journey, however its applicability is limited. Therefore, clinical practice within individual health services in Australia is largely dependent on the health service's local clinical guidelines. These guidelines are developed based on current evidence of smoking cessation therapy and hence often extend beyond TGA indications and PBS listings.

Current clinical guidelines include recommendations on the following approaches to smoking cessation that are not reflected in current TGA indications and/or PBS restrictions:

Combination nicotine replacement therapy (NRT)
Combining two forms of NRT, transdermal patches plus an intermittent form of therapy, has been shown to be more efficacious than using a single NRT dose form[7,8]. Patches provide a steady nicotine level whilst the other forms of NRT provide protection against breakthrough cravings reducing the risk of relapse. Combination NRT therapy is well evidenced in the literature and supported by clinical guidelines, however the current TGA indications and TGA approved consumer medicines information (CMIs) restricts the practice of some health professionals and influences the use of consumers. Current PBS restrictions indicating that treatment with patches *must be the sole PBS-subsidised therapy* for nicotine dependence, also limits clinicians to prescribing a single product resulting in either suboptimal treatment outcomes or out of pocket expenses for patients to whom cost may be a barrier for treatment.

Varenicline and NRT combination therapy
The RACGP guidelines recommend that patients attempting to quit smoking with varenicline accompanied by behavioural support, could be encouraged to use varenicline in combination with NRT as there is evidence of significantly higher abstinence rates than when varenicline is used alone[9,10]. Current TGA indications and PBS restrictions limit the use of varenicline as *the sole PBS-subsidised therapy* for nicotine dependence, once again placing cost as a barrier for optimum therapy.

Higher dose NRT and longer treatment duration
Whilst there is limited evidence for the use of higher dose and longer duration NRT, nationally recognised clinical guidelines recommend the use of these strategies[11,12]. This is however not reflected in current TGA indications or PBS restrictions which limit patients to *12 weeks of subsidised NRT per 12-month period and two courses for patients who identify as Aboriginal and Torres Strait Islander persons*. Hospital-based smoking cessation programs have varied use of PBS-listed medicines for smoking cessation on discharge. This may impact on the eligibility of patients' further access to PBS-listed medicines for smoking cessation once they return to the community, due to the restriction on duration of treatment. Once again, this discrepancy between evidence-based practice and regulatory restrictions may pose a significant barrier to successful smoking cessation and may disadvantage high-risk population groups.

Reduce to quit
Smoking is classified in the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)* as Tobacco Use Disorder, a chronic relapsing condition like all other substance use disorders. For this reason, smoking cessation should be perceived as a harm reduction strategy. Evidence suggests that NRT could help those who are not ready to quit to reduce their intake of tobacco, a positive step that could be a motivation to quitting[13]. The current TGA-approved 'cut down then stop' approach and the PBS restrictions limit use to patients who are attempting *to achieve abstinence from smoking*, rather than engaging a broader Australian population to improve their health by reducing their tobacco intake and supporting them to ultimately quit smoking.

SHPA recommends that the **PBS restrictions on current smoking cessation therapies are broadened to be in line with evidence based clinical guidelines including strategies such as combination therapy, higher doses and longer duration of treatment**. This change will support best practice smoking cessation

therapy being prescribed by clinicians and provide equitable subsidy for smoking cessation medicines used by patients experiencing nicotine dependence independent of their socio-economic circumstances. Consideration should be given to the impact of hospital-initiated smoking cessation programs on patient access to PBS subsidised medicines upon discharge and follow-up in the community setting.

SHPA also recommends that **additional intermittent forms of NRT such as inhaler and mouth spray, are added to the PBS**, providing clinicians and patients with the flexibility of choosing the most clinically appropriate form of therapy that best suits the patient's needs and enables them to achieve cessation.

Terms of Reference 4: Subject to the findings of Terms of Reference 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation.

Tobacco remains the leading preventable cause of morbidity and mortality in Australia[1], costing close to $137 billion annually of which approximately $7 billion directly relate to healthcare costs[14].

Smoking cessation therapies have been widely used in Australia and their safety and efficacy profiles are well established. The limited PBS expenditure of smoking cessation medicines is certainly cost-effective with evidence suggesting that the use of NRT to 'cut down to quit' being cost effective compared to no quit attempt[15]. However, the investment in PBS-subsidised smoking cessation therapies is not being optimised if it is not being utilised by health professionals with the most likely impact. Whilst we are seeing an increase in the number of hospitals providing smoking cessation programs, they are still limited and are not considered common practice. This is fundamentally due to lack of funding to support the implementation of these services, even though research shows that hospitals can have a significant impact on a patient's quit attempt.

The 2016 National Drug Strategy Household Survey (NDSHS) showed that for 44% of people who smoke tobacco, the main reasons they were trying to quit or change their smoking behaviour was because it was affecting their health. Hospitalisation can often be a significant impetus to making a quit attempt since patients are feeling vulnerable and are being encouraged by their healthcare professionals. The NDSHS 2016 shows that the most common source of referral for treatment episodes where nicotine was the principal drug of concern was a health service (37%).

SHPA members leading smoking cessation programs in their hospitals have reported significant positive impact on the average length of stay, complications and rate of readmission of patients to their local health services. However, they have also noted that current PBS restrictions are a substantial barrier to supporting patients to quit smoking. SHPA members report that patients who are provided with brief intervention counselling upon admission and evidence-based smoking cessation therapy throughout their hospital stay and upon discharge, often relapse when they have exhausted their hospital supply of medicines since they cannot access them via the PBS due to current unfounded restrictions.

In order to optimise the cost-effectiveness of PBS listed medicines for smoking cessation, SHPA recommends that current PBS restrictions should be expanded to align with best practice smoking cessation evidence and current clinical guidelines. This will ultimately allow all Australians who smoke to have access to these subsidised medicines in the way prescribed to them by their health professionals and provide them with a greater opportunity to successfully quit smoking, benefiting their health and the healthcare system as a whole.

Fundamentally, greater uptake of smoking cessation programs delivered by hospital pharmacists, who are the medication experts in Australian hospitals, would maximise the use of PBS-subsidised medicines to improve patient health outcomes and ultimately reduce the financial burden on Australia's healthcare system.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact [redacted]

Yours sincerely,

Kristin Michaels
Chief Executive

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